REMARKS / ARGUMENTS

Claims 1-16 are pending. In this amendment, claims 7 and 9 have been amended. New claims 10-16 have been added.

1. Priority Document

A copy of the priority document will be filed prior to payment of the issue fee.

2. Claims 7 and 9 as amended complies with 35 USC 101 and 112

Claims 7 is amended to claim a method of manufacture, and as such is compliant with 35 USC 101, as well as 35 USC 112.

Claim 9 has been amended to affirmatively recite steps set forth in the specification and Figure 1. Claims 10-16 claim further subject matter supported by the specification. No new matter is added by this amendment.

Withdrawal of the 35 USC 101 and 112, 2nd ¶ is requested.

3. No prima facie case of obviousness has been demonstrated

Claims 1-9 currently stand rejected as obvious under 35 USC 103, over EP 0780127 to Cramer. Applicant has considered the grounds as set forth by the Examiner, but respectfully disagrees with the conclusion of obviousness.

Cramer fails to teach each and every claim limitation of the instant claims, and therefore fails to render obvious the claimed invention. The active ingredient used in the present invention in each of the claims of this application is beclomethasone dipropionate anhydrate, not the monohydrate. As will be appreciated by those of ordinary skill, a monohydrate possesses characteristics and properties different than an anhydrate. In this respect, the examiner failed to cite an appropriate prior art reference.

The invention was mad in order to overcom problems associated with prior art formulations such as Aldecin AQ (see page 2 of the specification). Some ingredients such as dextrose, disodium hydrogen orthphosphate and citric acid are used in the formulation of the present invention to overcome irritancy problems. Moreover, BDP anhydrate is stabilized by using disodium hydrogen orthophosphate and citric acid (see lines 10 to 16 of page 3). The cited reference does not disclose or suggest these features. The superiority of the formulation over Aldecin AQ are demonstrated in Figs 4-6.

The Cramer reference describes a very broad range of formulation approaches, with various qualities expressed as end points. These general teaching do not suggest the invention as claimed in the present application, when the invention is taken as a whole. Applicant, has found that by employing the materials claimed in the present application, it is possible to make an aqueous suspension formulation having low irritancy, very good efficacy and surprisingly good preservation characteristics.

4. Conclusion

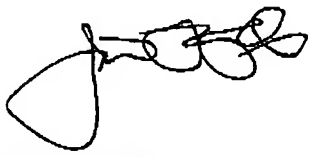
In light of the failure of Cramer to disclose each element in the claims under evaluation, applicant's assert that the examiner has failed to establish a prima facie case of non-obvious. Even assuming a prima facie case may be made out, the superiority of the formulation as claimed is evidence of the non-obviousness of the claimed invention.

Applicant requests that a timely Notice of Allowance be issued in this case. If any matters exist that preclude issuance of a Notice of Allowance, the examiner is requested to contact the applicant's representative at the number indicated below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge any fees or credit any overpayment, particularly including any fees required under 37 CFR Sections 1.16 and/or 1.17, and any necessary extension of time fees, to deposit Account No. 07-1392.

Application No. 10/049,167
Attorney Docket No. PJ3732USW

Respectfully submitted,



Dated: 15 Dec 2003

James P. Riek

Attorney for Applicant
Reg. No. 39,009
Tel. (919) 483-8022
Fax. (919) 483-7988

Customer No.: 23347